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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,079	07/02/2003	Ray C. Wasielewski	ORW01-GN003	5826
30074 7590 06/27/2007 TAFT, STETTINIUS & HOLLISTER LLP SUITE 1800 425 WALNUT STREET CINCINNATI, OH 45202-3957			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	10/612,079		WASIELEWSKI, RAY C.	
	Examiner		Art Unit	
	Anu Ramana		3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 41-46, 48-76 and 105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-46, 48-76 and 105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2007 has been entered.

### ***Claim Objections***

Claims 41, 63 and 105 are objected to because of the following informalities. It appears that "approximate" should be "proximate." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 63-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 63, the phrase "an inner surface of the femoral component at least partially defining the prosthetic intercondylar channel, and remote from native connective tissue" is confusing. It is suggested that the claim be reworded to clearly recite the structure being claimed.

In claim 64, the phrase, "for mounting the lining to at least one of the stabilizing post of the tibial component and the inner surface of the femoral component at least partially defining the prosthetic intercondylar channel" is

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confusing since it is a run-on sentence without clear recitation of structure being claimed using alternate phraseology.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41-46, 48-54 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferguson (US 6,592,622).

Ferguson discloses a band assembly or “prosthetic stabilizing device” 14 including a resorbable lining that is capable of being mounted to at least one of a tibial component 10 so that the lining is between the tibial component and a femoral component and proximate a prosthetic intercondylar channel (Figs. 1-4 and col. 5, lines 1-59). Note that Ferguson discloses that the prosthesis assembly of his invention can be used with an implanted femoral component which would have an intercondylar channel to interact with bearing insert 32 (col. 9, lines 65-67 and col. 10, lines 1-2).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41-46, 48-63, 65-76 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kampner (US 5,571,193) in view of Agrawal et al. (US 5,876,446).

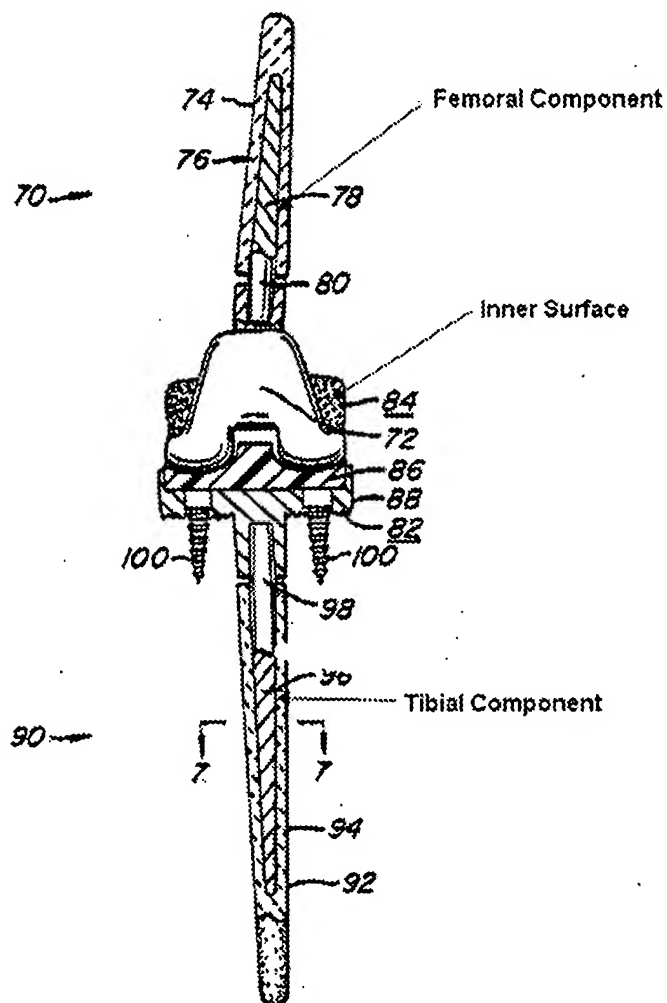
Kampner discloses a knee prosthesis including a femoral component 70 having an inner surface and a tibial component 90 (Fig. 4, col. 9, lines 15-67 and col. 10, lines 1-49). See marked up Figure 4 from Kampner on the following page.

Kampner discloses all elements of the claimed invention except for a lining mounted to an inner surface of the femoral component.

Agrawal et al. teach providing a coating or a lining on the tissue-mating surfaces of a prosthetic device for enhanced bio-fixation wherein the lining is made of a biodegradable polymer such as PLA or PGA including drugs and bone morphogenetic protein (col. 3, lines 13-35, col. 4, lines 16-67 and cols. 5-20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a lining as taught by Agrawal et al. on the inner surface of the Kampner femoral component to enhance bio-fixation of the femoral component.

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Claims 55, 56, 58, 59, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson (US 6,592,622) in view of Scarborough (US 6,616,698).

Ferguson discloses all elements of the claimed invention except for an antibiotic agent such as gentamicin, a clotting factor and osteogenic materials such as stem cells and transforming growth factors.

It is very well known to use gentamicin as an antibiotic and osteogenic materials such as stem cells and transforming growth factors in implants as evidenced by Scarborough (col. 6, lines 17-55).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an antibiotic such as gentamicin and osteogenic materials such as stem cells and transforming growth factors in the Ferguson implant, since it was well known to use these materials for their intended purpose, namely, promoting bone growth and prevention of infection.

### ***Allowable Subject Matter***

Claim 64 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments submitted under "REMARKS" in the response filed on June 13, 2007 have been fully considered.

Applicant's arguments with respect to the rejections of claims 41-54 and 60 are not persuasive for the following reason.

The limitation "remote from native connective tissue" only requires the lining to be "situated at some distance" from native connective tissue. Ferguson discloses that the band of resorbable material or "lining" 36 is positioned on the outside of band 34 making the lining remote from native connective tissue 30 (Fig. 2 and col. 5, lines 36-44).

Applicant's arguments with respect to claims 63, 65-76 and 105 are moot in view of the new grounds of rejection in this office action.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
June 22, 2007



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